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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,470	01/21/2000	MORTEN SOEGAARD	P01938US0	6355

26271 7590 12/04/2001  
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EXAMINER
EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/463,470**

Applicant(s)

**Soegaard et al.**

Examiner  
**G. R. Ewoldt**

Art Unit  
**1644**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Aug 23, 2001

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 35-84 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims 35-84 are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20)  Other: \_\_\_\_\_

**DETAILED ACTION**

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Gerald Ewoldt, Art Unit 1644, Technology Center 1600.

2. Applicant's election of Group I, Claims 35-50, in Paper No. 9, filed 6/14/01, is acknowledged. Upon reconsideration, however, the previous restriction requirement is vacated. A new restriction follows. The Examiner apologizes for any inconvenience or delay.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121 and 372:

I. Claims 35-50, drawn to a method for inactivating a target cell comprising bringing in contact a superantigen conjugated to a targeting moiety, a T cell, and an immune modulator.

II. Claims 35-37, and 39-49, drawn to a method for inactivating a target cell comprising bringing in contact a immune modulator conjugated to a targeting moiety, a T cell, and a superantigen.

III. Claims 35-50, drawn to a method for inactivating a target cell comprising bringing in contact a superantigen conjugated to a targeting moiety and an immune modulator, and a T cell.

IV. Claims 51-69 and 77-84, drawn to a superantigen conjugate and a pharmaceutical composition.

V. Claims 70-76, drawn to a DNA molecule.

4. The inventions listed do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

U.S. Patent No. 5,705,151 (1998) teaches a conjugate and a DNA comprising a superantigen and a cytokine (see particularly column 6, lines 10-18).

5. Accordingly, Groups I-V are not so linked as to form a single general inventive concept and restriction is proper.

6. Regardless of whichever Group Applicant should elect, Applicant is further required under 35 U.S.C. § 121 to elect:

A) A **specific** targeting moiety, such as one listed in Claim 41,

B) A **specific** superantigen, such as one listed on pages 1-2 of the specification, and further indicate whether said superantigen is modified or chimeric, and further indicate whether a **specific** B linker is desired, such as one listed in Claim 68,

C) A **specific** immune modulator, such as one listed in Claims 46 or 48, and list all Claims readable thereon including those subsequently added. Currently Claims 35, 51, 70, 76, and 77 are generic.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

G.R. Ewoldt, Ph.D.  
Patent Examiner  
Technology Center 1600  
November 30, 2001

*Patent J. Nolan*  
Patrick J. Nolan, Ph.D.  
Primary Examiner  
Technology Center 1600